UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,823	09/23/2005	Robert Baird Watson	P0003/7003	1778

21127 7590 09/19/2007

RISSMAN JOBSE HENDRICKS & OLIVERIO, LLP
ONE STATE STREET
SUITE 800
BOSTON, MA 02109

EXAMINER	
ANDERSON, MICHAEL J	
ART UNIT	**PAPER NUMBER**
3767	

MAIL DATE	DELIVERY MODE
09/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,823	WATSON, ROBERT BAIRD	
	Examiner	Art Unit	
	Michael J. Anderson	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-8, 12-19, 21-23 and 27-28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Malenchek (US patent No. 5,980,494) (Malenchek).

3. Claims 9-11, 20, and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Malenchek (US patent No. 5,980,494) (Malenchek).

4. With regard to claim 1, Malenchek discloses (figures 1-5) a syringe (2), including: a syringe casing (4); a syringe body (8) within the casing and defining a chamber for holding a charge of liquid (8), the syringe body being controllably moveable relative to the casing (column 5, lines 20-27); a hollow needle (36) connected to the syringe body for movement therewith and extending from the casing for use of the syringe; a plunger (6) reciprocally moveable within the body for drawing liquid into the body chamber and/or ejecting liquid from the body chamber through the needle (column 5, lines 7-27); and, control means enabling the syringe to draw and/or eject a charge of liquid through the needle, whereupon

movement of the syringe body and needle relative to the casing disables the syringe (column 6, lines 37-45).

5. With regard to claim 2, Malenchek discloses the safety syringe as for claim 1 above and further discloses wherein the syringe body is controllably movable relative to the casing from a position in which the syringe is enabled for drawing and/or ejecting the liquid charge, to a position in which the syringe is disabled preventing syringe use, and the control means (4) effects controlled movement of the body from the enabled position to the disabled position (column 5, lines 7-27 and column 6, lines 37-45).

6. With regard to claim 3, Malenchek discloses the safety syringe as for claim 2 above and further discloses wherein the syringe body is controllably movable from the enabled position to a disabling position in which the syringe is positioned for disablement, and then from the disabling position to the disabled position, and the control means effects controlled movement of the body through the disabling position (column 5, lines 7-27 and column 6, lines 37-45).

7. With regard to claim 4, Malenchek discloses the safety syringe as for claim 2 above and further discloses wherein the syringe casing and body are each elongate, and the syringe body is axially and rotatably slideable within the syringe casing, the syringe body sliding from the enabled position to the disabled position (column 5, lines 7-27 and column 6, lines 37-45).

8. With regard to claim 5, Malenchek discloses the safety syringe as for claim 2 above and further discloses wherein the syringe body is axially slidable into the disabled position, sliding of the syringe body into the disabled position

retracting the needle into the casing to thereby disable the syringe (column 5, lines 7-27 and column 6, lines 37-45).

9. With regard to claim 6, Malenchek discloses the safety syringe as for claim 2 above and further discloses wherein the control means includes at least one control member on the syringe casing, and at least one control member on the syringe body, the control members on the syringe casing and body inter-engaging during syringe use to thereby effect the controlled movement of the body (figure 1A, elements 4, 8, and 22).

10. With regard to claim 7, Malenchek discloses the safety syringe as for claim 6 above and further discloses wherein the control members include at least one control cam (10) and at least one cam follower (100), the cam and cam follower inter-engaging to effect the controlled movement of the body (figures 1A, 2, 7 and 8).

11. With regard to claim 8, Malenchek discloses the safety syringe as for claim 7 above and further discloses wherein the cam is located on the body, and the cam follower is located on the casing (column 4, lines 10-63, figures 1A, 2, and 7-13).

12. With regard to claim 9, Malenchek discloses the safety syringe as for claim 7 above and further discloses wherein the cam follower is a follower pin (122) (figures 7-21).

13. With regard to claim 10, Malenchek2 discloses the safety syringe as for claim 9 above and further discloses wherein the control cam is elongate and has

at least one profiled camming surface extending therealong for operative engagement by the cam follower (figures 1-3).

14. With regard to claim 11, Malenchek discloses the safety syringe as for claim 10 above and further discloses wherein the control cam includes a camming groove or slot for receiving the cam follower pin therein, the cam follower pin progressively travelling along the camming groove or slot causing relative movement between the syringe body and casing in response to the camming surface profile (figures 7-21).

15. With regard to claim 12, Malenchek discloses the safety syringe as for claim 7 above and further discloses wherein a single cam follower is provided, the single cam follower being located on an inner surface of the syringe casing and extending generally inwardly therefrom (column 4, lines 10-63, figures 1A, 2, and 7-13).

16. With regard to claim 13, Malenchek discloses the safety syringe as for claim 12 above and further discloses wherein a single control cam is provided, the single control cam being located at an outer surface of the syringe body in facing relation to the single cam follower during engagement therebetween (column 4, lines 10-63, figures 1A, 2, and 7-13).

17. With regard to claim 14, Malenchek discloses the safety syringe as for claim 7 above and further discloses wherein the control cam includes camming stages spaced there along, each with a respective camming surface with which the cam follower successively travels over to cause indexed movement of the

syringe body relative to the casing through each camming stage (column 4, lines 10-63, figures 1A, 2, and 7-13).

18. With regard to claim 15, Malenchek discloses the safety syringe as for claim 14 above and further discloses wherein the camming stages including one or more of: a. a charge draw camming stage during which a liquid charge is drawn into the body chamber; b. an air ejection camming stage during which air is ejected from the needle; c. a blood draw camming stage during which blood is drawn from a vein into the needle; and, d. a charge ejection camming stage during which a liquid charge is ejected from the body chamber, movement of the plunger during each camming stage forcing the follower into engagement with and to travel over the respective camming surface and thereby cause the syringe body to rotatably slide relative to the syringe casing (column 5, lines 7-62; column 4, lines 10-63, figures 1A, 2, and 7-13).

19. With regard to claim 16, Malenchek discloses the safety syringe as for claim 15 above and further discloses wherein the camming stages, when provided, are arranged in the order: a. charge draw camming stage, b. air ejection camming stage, c. blood draw camming stage, and d. charge ejection camming stage along the control cam (column 5, lines 7-62; column 4, lines 10-63, figures 1A, 2, and 7-13).

20. With regard to claim 17, Malenchek discloses the safety syringe as for claim 14 above and further discloses wherein the control cam includes detent stages adjacent the end of each of the camming stages for ending travel of the cam follower over the preceding camming stage and directing the cam follower

toward the successive camming stage (column 5, lines 7-62; column 4, lines 10-63, figures 1A, 2, and 7-22).

21. With regard to claim 18, Malenchek discloses the safety syringe as for claim 17 above and further discloses wherein each detent stage has a respective camming surface, the camming surfaces in the detent stages being angled relative to the camming surfaces in the preceding camming stages so as to redirect travel of the cam follower and cause the indexed movement of the syringe body through each camming stage (column 5, lines 7-62; column 4, lines 10-63, figures 1A, 2, and 7-22).

22. With regard to claim 19, Malenchek discloses the safety syringe as for claim 14 above and further discloses wherein the control cam includes a disabling camming stage during which the cam follower and cam disengage and the syringe body moves toward the disabled position (column 5, lines 7-62; column 4, lines 10-63, figures 1A, 2, and 7-22).

23. With regard to claim 20, Malenchek discloses the safety syringe as for claim 19 above and further discloses wherein the control cam includes a camming groove or slot, and the cam follower is a follower pin received in the camming groove or slot for progressive travel along the camming groove or slot causing relative movement between the syringe body and casing, the camming groove or slot having an open end through which the follower pin moves to exit from the camming groove or slot so as to release the syringe body for longitudinal sliding movement relative to the syringe casing to the disabled position and thereby retract the needle into the casing (figures 7-21).

24. With regard to claim 21, Malenchek discloses the safety syringe as for claim 19 above and further discloses a biasing means (12) acting on the syringe body to slidably move the body when in the disabling position to the disabled position (Abstract, column 5, lines 7-62; column 4, lines 10-63, figures 1A, 2, and 7-22).

25. With regard to claim 22, Malenchek discloses the safety syringe as for claim 21 above and further discloses wherein the biasing means includes a resilient biasing spring (12) acting between the syringe casing and body, to bias the body along the casing into the disabled position (Abstract, column 5, lines 7-62; column 4, lines 10-63, figures 1A, 2, and 7-22).

26. With regard to claim 23, Malenchek discloses the safety syringe as for claim 14 above and further discloses wherein the syringe body is moveable from an enabling position, in which the needle is retracted and housed within the casing, to the enabled position, and the control cam includes an enabling camming stage, movement of the syringe body to the enabled position causing the cam follower to engage the cam and travel over the camming surface of the enabling camming stage, the syringe body sliding along the casing so as to project the needle from the casing for use of the syringe (Abstract, column 5, lines 7-62; column 4, lines 10-63, figures 1A, 2, and 7-22).

27. With regard to claim 24, Malenchek discloses the safety syringe as for claim 23 above and further discloses wherein the control cam includes a camming groove or slot, and the cam follower is a follower pin, the camming groove or slot having an open end through which the follower pin moves to enter

the camming groove or slot so as to engage the camming surface of the enabling camming stage (figures 7-21).

28. With regard to claim 25, Malenchek discloses the safety syringe as for claim 11 above and further discloses wherein the camming groove or slot is of generally zig-zag configuration, and the camming and detent stages of the control cam are arranged on opposite sides of apical points of the camming groove or slot (figures 7-21).

29. With regard to claim 27, Malenchek discloses the safety syringe as for claim 2 above and further discloses a locking means acting on the body to prevent subsequent movement thereof relative to the casing when in the disabled position (Abstract, column 5, lines 7-62; column 4, lines 10-63, figures 1A, 2, and 7-22).

30. With regard to claim 28, Malenchek discloses the safety syringe as for claim 27 above and further discloses wherein the locking means includes at least one locking element on each of the syringe body and casing, the locking elements inter-engaging when the syringe body moves into the disabled position, thereby preventing further movement of the syringe body (Abstract, column 5, lines 7-62; column 4, lines 10-63, figures 1A, 2, and 7-22).

Claim Rejections - 35 USC § 103

31. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to

be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

32. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malenchek in view of Gibbs (US patent No. 5,085,640) (Gibbs).

33. With regard to claim 26, Malenchek discloses the safety syringe as for claim 2 above and further discloses wherein the syringe casing includes an access hole through which the needle extends during use of the syringe. However Malenchek does not disclose the access hole being offset from the needle so that when the needle is retracted into the casing into the disabled position, the retracted needle misaligning with the access hole so as to prevent re-extension of the needle from the casing. Gibbs teaches offsetting the needle from the hole when retracted (figure 42). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Malenchek and taught by Gibbs to provide an additional safety means for locking the needle in the syringe to prevent reuse or injury.

Response to Amendment

The present communication responds to the Amendment of 07/11/2007. By this communication, claim 1 was amended. The amendment **added** new matter. Claims 1-28 are pending. The rejection(s) are as stated.

Response to Arguments

34. Applicant's arguments filed 7/11/2007 have been fully considered but they are not persuasive. The amendment adds new matter to claim 1, which was not disclosed in the original specification. The phrase "wholly contained and retained" was not disclosed. In order for an application which does not expressly disclose a limitation to provide support for that limitation, the disclosure in the specification must be such that one skilled in the art would consider the presence of that limitation the necessary and only reasonable construction to be given the disclosure. In re Filstrup, Jr. (CCPA 1958) 251 F2d 850, 116 USPQ 440.

35. With regard to applicant's filing date arguments concerning claim 9-11, 20, and 24-25, the office concedes that Malenchek2 is not a proper reference. However, Malenchek (US patent No. 5,980,494), which is a proper reference also discloses the claimed features but instead calls the "pin" a "pawl".

36. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

37. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Anderson whose telephone number is (571) 272-2764. The examiner can normally be reached on M-F 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael J Anderson
Examiner
Art Unit 3767

MJA
9/13/2007

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons